UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 25, 2007

MEMORANDUM

SUBJECT: Review of "*Determination of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residue on the Hand from Treated Vinyl Flooring Sections Following Hand Press at Different Time Intervals*"

FROM: Dana Vogel, Senior Scientist
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TO: Cathryn O'Connell
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DP Barcode: 336759
PC Code: 069001
MRID Number: 46188615

Attached is a review of the MRID 46188615 "*Determination of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residue on the Hand from Treated Vinyl Flooring Sections Following Hand Press at Different Time Intervals*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the amount of residue left on a hand exposed to vinyl flooring immediately after application of a formulation containing pyrethrin (PY) and piperonyl butoxide (PBO) and after 3, 6, 9, and 16 days. The primary review for this study was conducted by Versar, Inc. A secondary review was conducted by the Health Effects Division (HED).

Results

Vinyl flooring sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40 in x 40 in wooden platforms. Application of the test material to the flooring was made using a sprayboom apparatus. The desired deposition rate of the test material onto the vinyl flooring was 3.96 $\mu g/cm^2$ for PY and 7.87 $\mu g/cm^2$ for PBO. Total deposition was measured

using deposition coupons, which were collected after application of the test material followed by a drying period. After collection of the deposition coupons, 24 vinyl flooring sections were removed and moved to a hand press room. The test subjects performed one hand press on a separate treated surface at each sampling interval. The subjects' hands were then cleaned with isopropyl alcohol dressing sponges to remove any transferred residues after each hand press. Removal of the test substance was also examined using dioctyl simulated saliva (DSS) and isopropyl alcohol (IPA) dressing sponges 16 days after application. The dressing sponges were extracted and then analyzed using GC/MS.

The study author reported residues for PY and PBO only if residues were above the LOQ. According to the study author, hand residues averaged 131.0 ± 64.9 ng/cm^2 for PY and 205.8 ± 98.5 ng/cm^2 for PBO immediately after application. Three days after application, the study author reported that residues transferred to the palm of the hand mostly fell below the LOQ and after six, nine and sixteen days after application, all residues were below the LOQ. The percent of PY and PBO residue transferred from the treated surface to the hands was reported by the study author to be 2.8% and 2.0%, respectively. Since the study author did not report residues that were below the LOQ, the percent transfer at the LOQ was reported instead. The percent of PY and PBO residue transferred from the vinyl flooring to the hands at the LOQ was reported to be 0.42% and 0.41%, respectively.

PYI residues sampes were corrected for a field fortification recovery of 86.5% and used ½ the LOQ for values reported to be below the LOQ. Mean corrected residues for PYI, PY and PBO immediately after application were 83.7 ± 41.5, 151.4 ± 75.0, and 205.8 ± 98.5 ng/cm^2, respectively. Mean corrected residues for PYI, PY and PBO three days after application were 10.9 ± 5.6, 19.7 ± 10.1, and 21.7 ± 4.2 ng/cm^2, respectively. At six, nine, and sixteen days after application, all residues were below the LOQ. The percent of PY and PBO residue transferred from the treated vinyl to the hands was estimated to be 2.3% and 1.3%, respectively. At three days after application, the percent transferred was 0.30% and 0.13% for PY and PBO, respectively.

For DSS wipes, the study author reported that all PBO residues were below the LOQ and 2 out of the 4 PY samples were below the LOQ. For IPA wipes, PY residues averaged 1.9 μg/sample, while PBO residues were all below the LOQ. DSS and IPA residues were corrected for recovery, correcting PYI residues for a field fortification recovery of 86.5% and using ½ the LOQ for residues reported to be below the LOQ. For DSS wipes, the corrected mean residues were calculated to be 0.74 ± 0.30, 1.34 ± 0.54, and 1.64 μg/sample for PYI, PY and PBO, respectively. For IPA wipes, the corrected mean residues were calculated to be 1.24 ± 0.17, 2.23 ± 0.31, and 1.64 μg/sample for PYI, PY and PBO, respectively. The percent of residue removed was only provided for PY residues on the IPA wipes (0.41%), since the study author did not report values for residues found to be below the LOQ. The percent of residue removed by DSS wipes was estimated to be 0.19% and 0.10% for PY and PBO, respectively. The percent removed by IPA wipes was estimated to be 0.32% and 0.10% for PY and PBO, respectively.

Conclusions

The primary review for this study was conducted by Versar, Inc. A secondary review was conducted by the Health Effects Division (HED). The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation,

Postapplication and Part C Guidelines were used to review the study. Overall, both the performance of this study and the data generated in this study conformed to the criteria set forth in the protocol and guidelines. HED believes the data within this study is of high quality and valid for risk assessment purposes.

Versar inc.

Reviewers: Kelly McAloon/Linda Phillips **Date: February 27, 2004**

STUDY TYPE: Active Transfer; Vinyl

TEST MATERIAL: Pyrethrin and Piperonyl Butoxide; pre-fill batch formulation (similar to that for an indoor fogger formulation)

SYNONYMS: Pyrethrin (PY) and Piperonyl Butoxide (PBO)

CITATION:

Author(s):	Sami Selim, Ph.D.
Study Director(s):	Robert E. Rogers, Ph.D, D.A.B.T., P.Biol.
Title:	*Determination of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residue on the Hand from Treated Vinyl Flooring Sections Following Hand Press at Different Times*
Study Completion Date:	August 25, 2002
Testing Facility:	Toxcon Health Sciences Research Centre Inc. 9607 - 41st Avenue Edmonton, Alberta Canada T6E 5XL
Analytical Facility:	Enviro-Test Laboratories/XENOS Division Unit 13 - 210 Colonnade Road Nepean, Ontario Canada K2E 7L5
Identifying Codes:	Toxcon Project Id: 00-041-PY01 Xenos Project No.: XEN00-39

SPONSOR: Non-Dietary Exposure Task Force

EXECUTIVE SUMMARY:

This report reviews "*Determination of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residue on the Hand from Treated Vinyl Flooring Sections Following Hand Press at Different Times*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the amount of residue left on a hand exposed to vinyl flooring immediately after application of a formulation containing pyrethrin (PY) and piperonyl butoxide (PBO) and after 3, 6, 9, and 16 days.

Three test rooms (Simulated Residential Rooms (SRRs)) were used, with one containing the application equipment (the sprayboom). Vinyl flooring sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40 in x 40 in wooden platforms. Application of the test material to the flooring was made using a sprayboom apparatus. The desired deposition rate of the test material onto the vinyl flooring was 3.96 $\mu g/cm^2$ for PY and 7.87 $\mu g/cm^2$ for PBO. Total deposition was measured using deposition coupons, which were collected after application of the test material followed by a drying period. After collection of the deposition coupons, 24 vinyl flooring sections were removed and moved to a hand press room. The test subjects performed one hand press on a separate treated surface at each sampling interval. The subjects' hands were then cleaned with isopropyl alcohol dressing sponges to remove any transferred residues after each hand press. Removal of the test substance was also examined using dioctyl simulated saliva (DSS) and isopropyl alcohol (IPA) dressing sponges 16 days after application. The dressing sponges were extracted and then analyzed using GC/MS.

The study author reported residues for PY and PBO only if residues were above the LOQ. According to the study author, hand residues averaged 131.0 ± 64.9 ng/cm^2 for PY and 205.8 ± 98.5 ng/cm^2 for PBO immediately after application. Three days after application, the study author reported that residues transferred to the palm of the hand mostly fell below the LOQ and after six, nine and sixteen days after application, all residues were below the LOQ.

The percent of PY and PBO residue transferred from the treated surface to the hands was reported by the study author to be 2.8% and 2.0%, respectively. Since the study author did not report residues that were below the LOQ, the percent transfer at the LOQ was reported instead. The percent of PY and PBO residue transferred from the vinyl flooring to the hands at the LOQ was reported to be 0.42% and 0.41%, respectively.

Versar corrected PYI residues for a field fortification recovery of 86.5% and used ½ the LOQ for values reported to be below the LOQ. Mean corrected residues for PYI, PY and PBO immediately after application were 83.7 ± 41.5, 151.4 ± 75.0, and 205.8 ± 98.5 ng/cm^2, respectively. Mean corrected residues for PYI, PY and PBO three days after application were 10.9 ± 5.6, 19.7 ± 10.1, and 21.7 ± 4.2 ng/cm^2, respectively. At six, nine, and sixteen days after application, all residues were below the LOQ. The percent of PY and PBO residue transferred from the treated vinyl to the hands was estimated by Versar to be 2.3% and 1.3%, respectively. At three days after application, the percent transferred was 0.30% and 0.13% for PY and PBO, respectively.

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The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.

- The test product was not identified and a label was not provided.
- Calibration procedures for the application equipment were not provided in the Study Report.
- The blank deposition coupon sample results were not provided in the Study Report.
- There was only one field fortification level.
- The study author did not correct the PY residue data for the field fortification recovery, which was below 90%.
- The results of the alpha cellulose coupons are provided in another study (Toxcon Study 00-35-PY01), however, this study refers to the incorrect set of samples (1 A/B to 1 W/X) in that study. The coupons used in this study were actually designated 3 A/B to 3 W/X in Toxcon Study 00-35-PY01.

COMPLIANCE:
Signed and dated GLP and Data Confidentiality statements were provided. A Quality Assurance statement was not provided in the Study Report, but was provided as part of the Analytical Phase Report in Appendix 3. The Study Report noted that the study was not performed according to the U.S. EPA FIFRA Good Laboratory Practice Regulations currently in effect (40 CFR, Part 160), however, all data collection and study conduct was performed "in the spirit of" the GLP standards. The data generated at Toxcon was not audited and the data and Analytical Report generated at Xenos were reviewed by Xenos' Quality Assurance representative.

GUIDELINE OR PROTOCOL FOLLOWED:

The study was conducted following Xenos and Toxcon Standard Operating Procedures and the protocol of the Non-Dietary Exposure Task Force (Toxcon Protocol No. 00-041-PY01).

I. MATERIALS AND METHODS

A. Materials:

1. Test Material:

Formulation:	An unidentified pre-fill formulation similar to that of an indoor fogger; developed by McLaughlin Gormley King Company (MGK); contains 0.774% pyrethrin (wt/wt) and 1.63% piperonyl butoxide (wt/wt)
Lot/Batch # formulation:	LPB47000b
Formulation guarantee:	Certificate of analysis provided
CAS #(s):	Pyrethrin: 8003-34-7
	PBO: 51-03-6
Other Relevant Information:	Toxcon ID No.: PY01T006

2. Relevance of Test Material to Proposed Formulation(s):

Pyrethrin and piperonyl butoxide are active ingredients used in formulated consumer products intended for use in residential buildings. The product used was a pre-fill batch formulation similar to that of an indoor fogger formulation developed by McLaughlin Gormley King Company (MGK). The name and label for the test product was not provided with the study.

B. Study Design:

There was one amendment and two deviations from the study protocol. The amendment was that gauze wipes wetted with either DSS solution or IPA were used to remove the formulated product from treated vinyl surfaces at Day 16 post application. This amendment allowed for the determination of the maximum amount of pesticide that may be removed from treated surfaces following an extended period post application. The two deviations included: (1) sample set X003901 demonstrated a R^2 value for PYI of 0.9778 which was slightly less than the SOP criteria ($\geq$0.98) and (2) the laboratory fortified sponge samples DS-F2 had recoveries less than the protocol criteria of 70-120% (67.2%). The Study Report states that these deviations were not expected to have an effect on the study.

1. Site Description:

Test locations:	The test site was located at the Toxcon Health Sciences Research Centre in Canada. Three test rooms (Simulated Residential Rooms (SRRs)) were used with one containing the application equipment (the sprayboom). The rooms were prepared according to Toxcon SOP No. E-025: *Preparation of Test Rooms Prior to an Experiment* and SOP No. M-026: *Masking of the Test Room and the Sprayboom Prior to an Experiment*.
Meteorological Data:	Target test room conditions prior to application included an air exchange rate of 0.6 ± 0.1 air change per hour (ACH), a temperature of 72 ± 4^{o}F and a relative humidity of 50 ± 10%.
Ventilation/Air-Filtration:	The ventilation system for the application room was turned off (dampers closed) during application and for three hours after application. The dampers were opened after the three hours and the room conditions were adjusted to reach the conditions prior to application for a 30 minute drying period.

2. Surface(s) Monitored:

Room(s) Monitored:	Three Simulated Residential Rooms (SRRs) were used. One room contained the sprayboom apparatus and treated vinyl flooring. The other two rooms were used to perform the hand press procedure.
Room Size(s):	16 ft x 16 ft x 8 ft
Types of Surface(s):	Vinyl flooring
Surface Characteristics:	Vinyl flooring sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40 in x 40 in wooden platforms. The vinyl flooring specifications were provided in the protocol. A total of 24 vinyl flooring sections were removed after application (and drying) and used for the hand press procedure.
Areas sprayed and sampled:	The vinyl flooring sections in one of the three SRRs used in this study were sprayed and sampled for pryrethrin and PBO residues.
Other products used:	N/A

3. Physical State of Formulation as Applied : Fogger

4. Application Rates and Regimes:

Application Equipment:	Sprayboom
Application Regime:	One sprayboom run conducted in one SRR.
Application rate(s):	An application rate was not provided in the Study Report. Application was based on the desired deposition rate of the test material onto the vinyl flooring. For pyrethrin, the desired deposition rate was 3.96 $\mu g/cm^2$ and for PBO, the desired deposition rate was 7.87 $\mu g/cm^2$. Deposition rates were based on results of indoor pyrethrin and PBO total release fogger deposition studies. The sprayboom nozzle sweep speed required to obtain the desired deposition was calculated using the following equation: $U = [(Q_t)(F_a)(k_1)/(R)(n)(d)(10^{-6})$, where U is the sprayboom nozzle sweep speed (cm/s),Q_t is the nozzle output rate (g/s), F_a is the fraction of pyrethrin in the formulation, R is the target deposition rate of PY ($\mu g/cm^2$), d is a fixed value representing the distance between nozzles (71.2 cm), n is the number of nozzles (5), and k_1 is a correction factor to account for formulation that is sprayed, but not deposited, on the test surface. The target speed was not provided in the Study Report but was reported to be documented in the raw data.
Equipment Calibration Procedures:	The Study Report states that a calibrated sprayboom was used in the study, but calibration procedures were not provided. It is not certain if the equipment used in this study was conducted with the proposed use for this product. A label was not provided with the study. Therefore, the label recommended application method is not known.
Was total deposition measured?	Total deposition was measured using deposition coupons. The deposition coupons consisted of squares of alpha cellulose (3 in x 3in). The coupons were backed with hexane-wiped heavy duty aluminum foil. The Study Report states that coupons were prepared according to Toxcon SOP No. M-015: *Preparation of Alpha Cellulose Deposition Coupon*. The coupons were present on the wooden platforms during test substance application.

D. Sampling:

Surface Areas Sampled:	Vinyl flooring sections present on wooden platforms in SRR.

Replicates per sampling interval: Two subjects participated in the study. Hand presses were performed with both the left and right hand of the test subjects. Each subject performed one hand press on a treated section of vinyl flooring at 0, 3, 6, 9, and 16 days following application of the test material. Each hand press used a new section of treated vinyl flooring (a total of 20 flooring sections were used). In addition, 4 vinyl flooring sections were sampled 16 days after application.

Number of sampling intervals: Five sampling intervals were conducted.

Method and Equipment: Residue deposition and transfer were determined using hand presses and deposition coupons. Additionally, transfer of PY and PBO after 16 days was determined using dressing sponges wetted with DSS and dressing sponges wetted with IPA.

Sampling Procedure(s) :

Deposition coupons - The deposition coupons were collected following a drying period after application of the test material. Disposable latex gloves were worn when the coupons were handled. The coupons were folded, so that the exposed side was on the inside, and then wrapped in hexane-wiped aluminum foil.

Hand residues - After application and collection of the deposition coupons, twenty-four vinyl flooring sections were removed and moved to a hand press room. Each section of vinyl flooring was placed in a hand press balance configuration at specific sampling intervals. The transfer of residues was determined based on the applied force (~8 kg) and contact duration (~20 s). The subjects washed and dried their hands prior to the hand presses. After the hand presses, the subjects' hands were cleaned with isopropyl alcohol dressing sponges. Hand palmer surface areas were determined using an ink image of the palm side of each hand, which was then scanned into a computer to create a digital image of the hand. The computerized methods of calculating surface areas are described in Toxcon SOP No. M-010.

Dressing Sponges - Dressing sponges wetted with either DSS or IPA were used to determine the amount of residue that could be removed from vinyl treated flooring 16 days after application. A 10 cm x 10 cm section of the treated flooring was wiped with the dressing sponges. About 5 mL of either the DSS or IPA was added to each dressing sponge (4 in x 4 in; 6-ply) prior to use. The vinyl section was first wiped with two DSS wetted dressing sponges and then two IPA wetted dressing sponges. A total of four dressing sponges were used per vinyl flooring section.

3. Sample Handling and Storage:

Dressing sponges collected from the hand wipes were placed in separate pre-labeled 180 mL glass jars with Teflon-lined lids. Deposition coupons were placed in aluminum containers and moved to freezer storage (<-10^{o}C) within 3 hours of collection. All samples were stored in the dark at <-10^{o}C until shipped for analysis. Samples were shipped to the analytical laboratory overnight in an insulated cooler with dry ice.

IV. ANALYTICAL METHODOLOGIES

A. Extraction method:

Dressing sponges: Extraction was performed by sonication and mechanical shaking of the dressing sponges at room temperature with ethyl acetate. One extraction was performed and the ethyl acetate was taken to dryness by rotary evaporation. Two clean-up steps were required for the sponges, including the use of a Discovery™ polyamide SPE cartridge and an Isolute

silica SPE cartridge. All sample extracts were taken to dryness and made up to an appropriate volume in toluene.

B. Detection methods: Analysis was performed using GC/MS in the EI/SIM mode. The method measured three Pyrethrin esters (PYI): Pyrethrin I (P-I), Cinerin I (C-I) and Jasmolin I (J-I) and PBO. See Table 1 for specific conditions.

Table 1. Gas Chromatographic and Mass Spectrometer Conditions

GC Column	DB-5, ~15 m x 0.25 mm ID, 0.25 μm film
GC/MS Mode	EI/SIM mode
MS Trap Set Temperature	225°C
Quantitating Ion	PYI esters = m/z 123 ion PBO = m/z 193 ion
GC Temperatures	Inlet: Initial - 120°C (hold 0.15 min) Prog 1 - 120-250°C @ 200°C/min (hold 10 min) Column: Initial - 90°C (hold 1.5 min) Prog 1 - 90-160°C @ 30°C/min Prog 2 - 160-175°C @ 1.8°C/min Prog 3 - 175-210°C @ 2.0°C/min Prog 4 - 210-320°C @ 50°C/min (hold 15 min) Transfer line: 280°C
Carrier Gas Flow Rate	~1.3 mL/min (constant)
Mass Spectrometer Interface	direct capillary interface
Injector Split	0 min, split ON, split ratio: 10 0.25 min, split OFF 2.00 min, split ON, split ratio: 100
Injection Volume	5.0 μL direct injection
Rate	0.4 μL/sec
Approximate Retention Times	C-I ~ 17 min J-I ~ 20 min P-I ~ 21 min PBO ~ 23 min

D. Method Validation:

The analytical methods were validated in a previous study. The Study Report states that validation data for the limit of quantitation (LOQ) was taken from Xenos report XEN00-14. The LOQ is reported for PYI, PY and PBO (see Table 2).

Table 2. Validated LOQs

Formulation	PYI	PY	PBO
200 μg	0.882 μg	1.58 μg	3.20 μg

Instrument performance and calibration: Calibration solutions were prepared from the formulation by dilution in toluene. A total of 5 concentration were used to calibrate the system:

0.010, 0.020, 0.040, 0.075, and 0.100 μg/μL. The GC/MS response was determined using the prepared calibration standards to perform a linear regression analysis.

E. Quality Control:

Lab Recovery: To obtain recovery and method performance data, concurrent laboratory control samples were fortified with the formulated product. Samples were fortified at the LOQ, 2x LOQ, 5x LOQ, and 100x LOQ. Results from the laboratory fortified samples are summarized in Table 3. Overall average recoveries were 81.4 ± 16.0% for PYI and 92.6 ± 10.9% for PBO.

Field Fortification: Samples of the dressing sponges and deposition coupons were fortified with an amount of stock solution equivalent to 10 μg of PBO and 500 μg of PBO, respectively. Duplicate samples were prepared and exposed for approximately 3 hours under the same conditions as the test samples. These samples were stored and analyzed with the test samples. Field fortification results for the dressing sponges are summarized in Table 4. Overall average recoveries were 86.5 ± 4.03% for PYI and 109 ± 0.71% for PBO. The Study Report stated that field fortification samples of the alpha cellulose deposition coupons were also prepared, but the results are provided in another study (Toxcon Study # 00-35-PY01).

Control Samples: Blank samples of dressing sponges and alpha cellulose coupons were prepared. A volume of solvent approximately equal to the largest volume of solution used in the fortifications was added to samples of dressing sponges and coupons. Of four control dressing sponge samples, apparent PYI residues were found in two of them. The Study Report stated that the response was less than the responses of combined PYI esters in the lowest standard injected. Therefore, quantitation of the residues was carried out by extrapolating the calibration curve. The resulting PYI residues were below the LOQ. No detectable PBO residues were found in the blank samples.

Storage Stability: The field fortified samples were analyzed after a period of 25 days. The Study Report stated that this confirmed the stability of the residues over this time period.

V. RESULTS

Versar corrected residue data for field fortification recoveries below 90%. The study author did not correct for field fortification recoveries. Residues were reported for both PYI and PBO, as well as PY, which is total pyrethrin calculated from the PYI data by using a conversion factor (1.808) derived from the percentages of total pyrethrins and PYI in the formulated product.

A. Alpha Cellulose and Deposition of Formulation:

The Study Report states that the results of the analysis of the deposition coupons were reported in a different report (Toxcon Study 00-35-PY01). The overall mean for PY is reported as 4.66 ± 0.99 µg/cm^2 and for PBO as 10.2 ± 1.87 µg/cm^2. The achieved deposition rate is reported to be 118% of the target deposition rate for PY and 130% of the target deposition rate for PBO. Versar examined the coupon residue data reported in Toxcon Study 00-35-PY01 and found that the field fortificaiton recoveries for the deposition coupons were below 90%. Recoveries averaged 70.3% for PYI and 62.8% for PBO. Versar corrected the deposition coupon residue data. Corrected residues were calculated by Versar to be 6.63 ± 1.40 µg/cm^2 for PY and 16.21 ± 2.97 µg/cm^2 for PBO. The achieved deposition rate using these values is 169% for PY and 206% for PBO. The corrected deposition values were used by Versar in calculating the percent of PY and PBO residues transferred from the vinyl flooring to the hands.

Table 3. Summary of Concurrent Laboratory Fortification Recoveries

Matrix	Fortification Level (µg)		Measured Residue (µg/sample)		Percent Recovery (%)		Average Recovery (%)		Std. Dev.		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing sponge	LOQ										81.4	92.6	16.0	10.9	19.7	11.8
	0.836	3.28	0.868	3.51	104	107	99.6	105	6.77	3.21						
			0.861	3.48	103	106										
			0.767	3.31	91.8	101										
	2x LOQ															
	1.67	6.56	1.28	5.90	76.2	89.9	76.2	89.9	---	---						
	5x LOQ															
	4.18	16.4	2.81	13.2	67.2	80.6	71.2	85.6	4.21	5.63						
			2.96	13.9	70.8	84.5										
			3.16	15.0	75.6	91.7										
	100x LOQ															
	83.6	328	52.6	263	62.9	80.1	62.9	80.1	---	---						

Table 4. Summary of Field Fortification Recoveries.

Matrix	Fortification Level (µg)		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing sponge	2.56	10	2.14	10.9	83.6	109	86.5	109	4.03	0.707	4.66	0.652
			2.29	10.9	89.3	108						

B. Hand Residues:

Total hand residues were calculated by the study author for each hand of the test subjects at 0, 3, 6, 9, and 16 days after application. Residues are reported for PY and PBO only if residues were above the LOQ. According to the study author, hand residues averaged 131.0 ± 64.9 ng/cm^2 for PY and 205.8 ± 98.5 ng/cm^2 for PBO immediately after application. Three days after application, the study author reported that residues transferred to the palm of the hand mostly fell below the LOQ, and after six, nine and sixteen days after application, all residues were below the LOQ.

Versar corrected PYI residues for a field fortification recovery of 86.5% and used ½ the LOQ for values reported to be below the LOQ. Mean corrected residues for PYI, PY and PBO immediately after application were 83.7 ± 41.5, 151.4 ± 75.0, and 205.8 ± 98.5 ng/cm^2, respectively. Mean corrected residues for PYI, PY and PBO three days after application were 10.9 ± 5.6, 19.7 ± 10.1, and 21.7 ± 4.2 ng/cm^2, respectively. At six, nine, and sixteen days after application, residues were all below the LOQ.

The percent of residue transferred to the hands after contact with treated flooring surfaces was calculated as the ratio of the amount of residue present on the hand divided by the average residue found on the alpha cellulose coupons. The uncorrected residue found on the coupons was reported to be 4.66 μg/cm^2 for PY and 10.2 μg/cm^2 for PBO. When corrected for field fortification recoveries, the coupon residues averaged 6.63 μg/cm^2 for PY and 16.21 μg/cm^2 for PBO. The percent of residue transferred to the hands after application was reported by the study author to be 2.8% for PY and 2.0% for PBO. Since the study author did not report residues that were below the LOQ, the percent transfer at the LOQ was reported instead. For PY and PBO, the percent transfer at the LOQ was reported to be 0.42% and 0.41%, respectively. The percent of PY and PBO residue transferred after application calculated by Versar was 2.3% and 1.3%, respectively. At three days after application, the percent transferred was 0.30% and 0.13% for PY and PBO, respectively.

C. DSS and IPA Wipe Residues:

The residues transferred to the DSS and IPA sponges were also calculated by the study author. For DSS wipes, the study author reported that all PBO residues were below the LOQ and 2 out of the 4 PY samples were below the LOQ. For IPA wipes, PY residues averaged 1.9 μg/sample, while PBO residues were all below the LOQ. Versar also calculated DSS and IPA residues, correcting PYI residues for a field fortification recovery of 86.5% and using ½ the LOQ for residues reported to be below the LOQ. For DSS wipes, the corrected mean residues were calculated to be 0.74 ± 0.30, 1.34 ± 0.54, and 1.64 μg/sample for PYI, PY, and PBO, respectively. For IPA wipes, the corrected mean residues were calculated to be 1.24 ± 0.17, 2.23 ± 0.31, and 1.64 μg/sample for PYI, PY, and PBO, respectively.

The percent of residue removed by the DSS and IPA wipes from the treated flooring surfaces was calculated as the ratio of the amount of residue present on the wipes divided by the average residue found on the alpha cellulose coupons. Since the study author did not report values for residues found to be below the LOQ, the percent removed was only provided for PY residue on the IPA wipes (0.41%). The percent removed by DSS wipes calculated by Versar was 0.19% and 0.10% for PY and PBO, respectively. The percent removed by IPA wipes was 0.32% and 0.10% for PY and PBO, respectively.

VI. CONCLUSION

Residues remaining on hands following contact with a treated vinyl flooring surface following application and at 3, 6, 9, and 16 days after application were determined for two test subjects. In addition, the study author calculated the amount of residue removed by DSS and IPA wipes after hand press treatments. The percent of residue transferred to the hands after application was reported by the study author to be 2.8% for PY and 2.0% for PBO. The percent of residue transferred at the LOQ was reported to be 0.42% and 0.41% for PY and PBO, respectively. For DSS wipes, the study author reported that all PBO residues were below the LOQ and 2 out of the 4 PY samples were below the LOQ. For IPA wipes, PY residues averaged 1.9 μg/sample, while PBO residues were all below the LOQ. Since the study author did not report values for residues found to be below the LOQ, the percent removed was only provided for PY residue on the IPA wipes (0.41%).

Versar also calculated hand residues and wipe residues based on the data provided for dressing sponges and hand surface area measurements. The percent transferred for PY and PBO after application calculated by Versar was 2.3% and 1.3%, respectively. At three days after application, the percent transferred was 0.30% and 0.13% for PY and PBO, respectively. The percent removed by DSS wipes calculated by Versar was 0.19% and 0.10% for PY and PBO, respectively. The percent removed by IPA wipes was 0.32% and 0.10% for PY and PBO, respectively.

LIMITATIONS OF THE STUDY:

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.

- The test product was not identified and a label was not provided.
- Calibration procedures for the application equipment were not provided in the Study Report.
- The blank deposition coupon sample results were not provided in the Study Report.
- There was only one field fortification level.
- The study author did not correct the PY residue data for the field fortification recovery, which was below 90%.
- The results of the alpha cellulose coupons are provided in another study (Toxcon Study 00-35-PY01), however, this study refers to the incorrect set of samples (1 A/B to 1 W/X) in that study. The coupons used in this study were actually designated 3 A/B to 3 W/X in Toxcon Study 00-35-PY01.

Table 5. Summary of Pyrethrin and PBO Dry Hand Press Results on Vinyl Flooring

Replicate	Days after Application[a]	Measured Residue (µg/sample)			Field fortification Recovery (%)		Corrected Residue (µg/sample)			Hand Surface Area (cm^2)[d]	Corrected Residue (ng/cm^2)[e]			% of Application[f]	
		PYI	PY[b]	PBO	PYI	PBO	PYI	PY[b]	PBO[c]		PYI	PY	PBO	PY	PBO
1(BRR)	0	2.80	5.06	8.54	86.5	109	3.24	5.85	8.54	96.80	33.4	60.5	88.2	0.91	0.54
2 (BRL)	0	4.81	8.70	13.60	86.5	109	5.56	10.05	13.60	84.00	66.2	119.7	161.9	1.80	1.00
3 (MML)	0	6.52	11.79	18.10	86.5	109	7.54	13.63	18.10	66.00	114.2	206.5	274.2	3.11	1.69
4 (MMR)	0	6.69	12.10	19.10	86.5	109	7.73	13.98	19.10	63.90	121.0	218.8	298.9	3.30	1.84
Mean							6.02	10.88	14.84		83.7	151.4	205.8	2.30	1.30
Standard Deviation							2.10	3.79	4.83		41.5	75.0	98.5	1.13	0.61
1(BRR)	3	<LOQ[g]	<LOQ	<LOQ	86.5	109	0.48	0.87	1.64	96.80	5.0	9.0	16.9	0.14	0.10
2 (BRL)	3	1.13	2.04	<LOQ	86.5	109	1.31	2.36	1.64	84.00	15.6	28.1	19.5	0.42	0.12
3 (MML)	3	<LOQ	<LOQ	<LOQ	86.5	109	0.48	0.87	1.64	66.00	7.3	13.2	24.8	0.20	0.15
4 (MMR)	3	0.87	1.58	<LOQ	86.5	109	1.01	1.82	1.64	63.90	15.8	28.5	25.7	0.43	0.16
Mean							0.82	1.48	1.64		10.9	19.7	21.7	0.30	0.13
Standard Deviation							0.41	0.74	---		5.6	10.1	4.2	0.15	0.03

a Results are only presented for 0 and 3 days after application since the residues after day 3 were all below the LOQ.

b PY is total pyrethrin calculated by using a conversion factor (1.808) derived from the percentages of total pyrethrins and PYI in the formulated product.

c No correction needed since recovery is above 90%.

d Based on the hand palmer surface area measurements.

e Corrected residue based on hand surface area and converted from $\mu g/cm^2$ to ng/cm^2.

f Calculated as the ratio of the amount of residue present on the hand divided by the average residue found on the alpha cellulose coupons (4.66 $\mu g/cm^2$ for PY and 10.2 $\mu g/cm^2$ for PBO corrected to 6.63 $\mu g/cm^2$ for PY and 16.21 $\mu g/cm^2$ for PBO based on field fortification recovery data of 70.3% for PYI and 62.8% for PBO).

g ½ the LOQ was used in calculations for residue values reported to be <LOQ (LOQ PYI = 0.836 μg/sample; LOQ PY = 1.51 μg/sample; LOQ PBO = 3.28 μg/sample).

Table 6. Summary of Pyrethrin and PBO DSS and IPA Wipe Results on Vinyl Flooring

Replicate	Days after Application	Measured Residue (µg/sample)			Field fortification Recovery (%)		Corrected Residue (µg/sample)			Sponge Surface Area (cm^2)[c]	Corrected Residue (ng/cm^2)[d]			% of Application[e]	
		PYI	PY[a]	PBO	PYI	PBO	PYI	PY[a]	PBO[b]		PYI	PY	PBO	PY	PBO
DSS-1	16	0.893	1.61	<LOQ	86.5	109	1.03	1.87	1.64	104.0	9.9	17.9	15.8	0.27	0.10
DSS-2	16	<LOQ	<LOQ	<LOQ	86.5	109	0.48	0.87	1.64	104.0	4.6	8.4	15.8	0.13	0.10
DSS-3	16	0.843	1.52	<LOQ	86.5	109	0.97	1.76	1.64	104.0	9.4	16.9	15.8	0.26	0.10
DSS-4	16	<LOQ	<LOQ	<LOQ	86.5	109	0.48	0.87	1.64	104.0	4.6	8.4	15.8	0.13	0.10
Mean							0.74	1.34	1.64		7.1	12.9	15.8	0.19	0.10
Standard Deviation							0.30	0.54	---		2.9	5.2	---	0.08	---
IPA-1	16	1.16	2.10	<LOQ	86.5	109	1.34	2.42	1.64	104.0	12.9	23.3	15.8	0.35	0.10
IPA-2	16	1.14	2.06	<LOQ	86.5	109	1.32	2.38	1.64	104.0	12.7	22.9	15.8	0.35	0.10
IPA-3	16	1.13	2.04	<LOQ	86.5	109	1.31	2.36	1.64	104.0	12.6	22.7	15.8	0.34	0.10
IPA-4	16	0.84	1.53	<LOQ	86.5	109	0.98	1.76	1.64	104.0	9.4	17.0	15.8	0.26	0.10
Mean							1.24	2.23	1.64		11.9	21.5	15.8	0.32	0.10
Standard Deviation							0.17	0.31	---		1.7	3.0	---	0.05	---

a PY is total pyrethrin calculated by using a conversion factor (1.808) derived from the percentages of total pyrethrins and PYI in the formulated product.

b No correction needed since recovery is above 90%.

c Based on dressing sponge measurements (10.2 cm x 10.2 cm).

d Corrected residue based on sponge surface area and converted from $\mu g/cm^2$ to ng/cm^2.

e Calculated as the ratio of the amount of residue present on the hand divided by the average residue found on the alpha cellulose coupons (4.66 $\mu g/cm^2$ for PY and 10.2 $\mu g/cm^2$ for PBO corrected to 6.63 $\mu g/cm^2$ for PY and 16.21 $\mu g/cm^2$ for PBO based on field fortification recovery data of 70.3% for PYI and 62.8% for PBO).

f ½ the LOQ was used in calculations for residue values reported to be <LOQ (LOQ PYI = 0.836 μg/sample; LOQ PY = 1.51 μg/sample; LOQ PBO = 3.28 μg/sample).